REMARKS

Responsive to the outstanding Official Action mailed December 28, 2007, applicant respectfully requests the re-examination and reconsideration of the present application pursuant to 37 CFR 1.121.

In the outstanding Official Action, claims 20-25 were rejected under 35 USC §102(b) as allegedly being anticipated by MCHUGH. This rejection is traversed.

As the Examiner is aware, a claim is anticipated only if each and every recitation as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicant does not believe that MCHUGH discloses or suggests any of the steps necessary for preparing an immunoreagent for a calibration system applied to the assaying of multiple analytes in a biological sample.

Indeed, the Examiner is respectfully reminded that applicant does not claim a process for the simultaneous quantitation of several analytes in a sample by Flow Microsphere Immunoassay (FMIA). Rather, the claimed invention is directed to a specific method for the preparation of an immunoreagent, which is used to make a calibration system for such a quantitation.

For example, the present invention generally utilizes the following steps:

a1- creating a set of categories of particles C_1L_1, C_2L_1, C_3L_1,...C_nL_1 and associating with the particles, a set of concentrations C_1, C_2, C_3,...C_n of a given ligand L_1 for a given analyte;

a2- contacting each category of particles C_1L_1, C_2L_1, C_3L_1,...C_nL_1 with a range of concentrations K_1, K_2, K_3,...K_n of homologous compound H_1 and plotting the response signal as a function of said range of concentrations K_1, K_2, K_3,...K_n and obtaining a corresponding number of curves, e.g.,:

curve C_1L_1/K_1, curve C_1L_1/K_2, curve C_1L_1/K_3,...curve C_1L_1/K_n,

curve C_2L_1/K_1, curve C_2L_1/K_2, curve C_2L_1/K_3,...curve C_2L_1/K_n,

curve C_3L_1/K_1, curve C_3L_1/K_2, curve C_3L_1/K_3,...curve C_3L_1/K_n,

curve C_nL_1/K_1, curve C_nL_1/K_2, curve C_nL_1/K_3,...curve C_nL_1/K_n;

a3- carrying out steps a1-a2 for as many ligands L_2, L_3, L_4,...L_n as analytes to be quantified in the test sample and obtaining a corresponding number of curves;

b1- selecting among the set of curves obtained in step a2 a (Curve?L_1) that corresponds to the smallest concentration of the ligand L_1. This provides a significant response signal that ensures reading precision over the range of concentrations and which is compatible with the use of a sample dilution and of a labeling reagent which are common to all the analytes simultaneously assayed;

b2- carrying out a selection as in step b1 among each set of curves obtained in step a3 to obtain the smallest

concentrations of the ligand L_2, L_3,...L_n which gives a significant response signal as in step b1;

c- identifying in the selected curves (Curve?L_1, Curve?L_2, Curve?L_3,...Curve?L_n), the signal (so called "mean signal") associated with a point characteristic of each curve, and obtaining a series of mean signals S_1, S_2, S_3,...S_n;

d- adjusting, where appropriate, the amounts of ligands L_1, L_2, L_3,...L_n such as the mean signal S_1, S_2, S_3,...S_n, are within a ratio of 1 to 5; and

e- mixing the categories C?L_1, C??L_2, C???L_3,...C????L_n of particles which correspond to the criterion of step d.

The present invention is thus based on a series of selection steps and, if needed, an adjusting step so that the mean signals given by the various categories of particles are within a ratio of 1 to 5, which permits a single calibration step for all the analytes rather than utilizing as many calibration steps as analytes.

This stands in contrast to MCHUGH. MCHUGH discloses the quantitative and simultaneous detection of multiple analytes. Concerning calibration, MCHUGH discloses the use of a standard curve per analyte (page 589: "When measuring analytes such as soluble antigens, a standard curve is generally used to determine analyte concentration. Microspheres are coated with antibody to the analyte to be measured and known concentrations of the analyte are added and followed by a fluorescent anti-analyte

reagent. The fluorescent signal is plotted against the known analyte concentrations and the concentration of analyte in unknown samples is determined from the standard curve").

In other words, there are as many standard curves as analytes and the use of these multiple standard curves is needed for the simultaneous detection of multiple analytes.

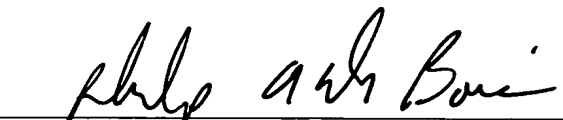
Thus, in view of the above, applicant respectfully submits that the MCHUGH publication fails to anticipate the claimed invention.

In view of the present amendment and the foregoing remarks, therefore, applicant believes that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



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